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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,987	09/11/2000	John P. Vanden Heuvel	7024465PUR99	9345

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,987

Applicant(s)

VANDEN HEUVEL ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>24</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The outstanding rejections of claim 22 under 35 USC 112, second paragraph, are withdrawn in view of the Applicant's remarks filed November 25, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boer et al. (US Patent 5,518,751) in view of Cook et al. (US Patent 5,554,646 from the IDS received September 6, 2000).

de Boer et al. teaches that unsaturated fatty acid, preferably CLA, in food compositions such as milk products are useful in treating disorders such as diabetes (See particularly col. 1, line 35 to 43).

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de Boer et al. does not expressly teach particularly CLA is useful in a method of treating diabetes. de Boer et al. does not expressly teach that the conjugated linoleic acid is *trans,cis-9,11-octadecadienoic acid*, *cis,cis-9,11-octadecadienoic acid*, or *trans,cis-10,12-octadecadienoic acid* can be incorporated into a composition such as a food composition. de Boer et al. does not expressly teach that the amount of the conjugated linoleic acid is about 1mg to about 10,000mg/kg of body weight in the invention.

Cook et al. teaches a method of adding conjugated linoleic acid (CLA) compounds into animal feed to reduce fat in the animal (see particularly claim 1). Cook et al. also teaches the conjugated linoleic acid compounds to be used may include *trans,cis-9,11-octadecadienoic acid* or *cis,cis-9,11-octadecadienoic acid* or *trans,cis-10,12-octadecadienoic acid* (See particularly col. 4, line 48 to col.5 line 8). Cook et al. also teaches the amount of CLA be employed as 0.001g/kg to 1g/kg (See col. 5, line 9-13).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetes. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans, cis-9,11-octadecadienoic acid* or *cis,cis-9,11-octadecadienoic acid* or *trans,cis-10,12-octadecadienoic acid* into a milk composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetes because de Boer et al. clearly teaches unsaturated fatty acids

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preferably CLA are useful to treat disorders including diabetes (See particularly col. 1, line 35 to 43). Therefore, employing CLA would have been reasonably expected to be useful to treat diabetes.

One of ordinary skill in the art would have been motivated to incorporate the CLA compounds herein in the amounts herein into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are known to be useful in a method and composition for treating diabetes. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds including the compounds herein in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments regarding rejections over de Boer et al. in view of Cook et al.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA

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1971). In the instant case, as discussed in the previous office actions before, de Boer clearly teaches unsaturated fatty acid, preferably conjugated linoleic acid, is useful in treating diabetes.

Applicant's remarks filed November 25, 2002 regarding the request for the examiner to cite additional references to support the examiner's position have been considered but are not found persuasive. Please note that this is the applicant's burden, not the examiner's, to provide evidence to show that one of ordinary skill in the art at the time the invention was made will not be motivated to employ conjugated linoleic acid to treat diabetes. In the instant case, Applicant fails to provide any evidence to show that the state of the art at the time the invention was made will draw away one of ordinary skill in the art to employ the herein claimed compound in the herein claimed method.

Applicant's rebuttal arguments filed November 25, 2002 averring Cook's failure to obviate the deficiencies have been considered, but are not found persuasive. Cook was cited to illustrate that CLA was known to be added into food products. Therefore, adding CLA into animal food products would have been obvious.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Semenkovich and Heinecke (Diabetes, 1997;46:327-334) in view of Steinhart (Journal of Chemical Education, 1996; 73(12):A302) and Cook et al.

Semenkovich and Heinecke teaches most diabetic patients die from macrovascular complications. Semenkovich and Heinecke also teaches that oxidative modification of lipoproteins in diabetic patients is enhanced; with this being one of the

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major risk of developing cardiovascular complications (macrovascular complication) in diabetic patients (See the abstract, also page 330, col. 1, second paragraph).

Semenkovich and Heinecke also teaches that antioxidants as potent inhibitors of lipoprotein lipid peroxidation and thereby reduce the lipoprotein oxidation products and cytotoxicity caused by those products (See particularly page 330, col. 1, second paragraph).

Semenkovich and Heinecke does not expressly teach the employment of CLA in a method to treat diabetes, or the symptoms of diabetes. Semenkovich and Heinecke does not expressly teach that the conjugated linoleic acid is *trans,cis*-9,11-octadecadienoic acid, *cis,cis*-9,11-octadecadienoic acid, or *trans,cis*-10,12-octadecadienoic acid can be incorporated into a composition such as food composition. Semenkovich and Heinecke does not expressly teach the amount of the conjugated linoleic acid as about 1mg to about 10,000mg/kg of body weight in the invention.

Steinhart teaches that CLA is a natural antioxidant (See page 3, last paragraph; also page 5, last paragraph).

Cook et al. teaches a method of adding conjugated linoleic acid (CLA) compounds into animal feed to reduce fat in the animal (see particularly claim 1). Cook et al. also teaches the conjugated linoleic acid compounds to be used may include *trans,cis*-9,11-octadecadienoic acid or *cis,cis*-9,11-octadecadienoic acid or *trans,cis*-10,12-octadecadienoic acid (See particularly col. 4, line 48 to col.5 line 8). Cook et al. also teaches the amount of CLA be employed as 0.001g/kg to 1g/kg (See col. 5, line 9-13).

It would have been obvious to one skill in the art when the invention was made to employ CLA in a method of treating diabetes. It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate about 1mg to about 10,000mg/kg of body weight of the *trans, cis*-9,11-octadecadienoic acid or *cis, cis*-9,11-octadecadienoic acid or *trans, cis*-10,12-octadecadienoic acid into a food composition product useful in a method of treating diabetes.

One of ordinary skill in the art would have motivated to employ CLA in a method of treating diabetes because administering CLA to diabetic patients would have been reasonably expected to be useful in reducing the macrovascular complications in such patients due to CLA's known antioxidant effect. Reducing complications of the disease would be reasonably expected to be useful as an adjunctive treatment modality.

One of ordinary skill in the art would have been motivated to incorporate the specific CLA compounds herein, in the amounts herein recited, into milk food composition products useful in a method of treating diabetes because CLAs, broadly, are reasonably expected to be useful in a method and composition for treating diabetes as discussed above. Therapeutic effects in the treatment of diabetes would have been reasonably expected when using any particular known CLA compounds, including those specific CLA compounds herein, in a composition or method to treat diabetes.

Optimization of result effect parameters (e.g., amount and concentrations of composition ingredients to be employed) is obvious as being within the skill of the artisan, absent evidence to the contrary.

Response to Arguments regarding rejections over Semenkovich and Heinecke in view
of Steinhart and Cook et al.

Applicant's rebuttal arguments filed November 25, 2002 averring the cited prior art's failure to teach the employment of CLA to treat diabetes *per se* have been considered, but are not found persuasive. One of ordinary skill in the art would recognize treatment of a disease including eradicating the root cause of the disease as well as relief of symptoms that directly or indirectly caused by the same disease. In the instant case, macrovascular complication such as atherosclerosis is a well known complication caused by diabetes. Treating such complication of diabetes would be considered relieving the symptoms or damages caused by diabetes. Therefore, employing an old and well-known antioxidant, CLA, to slow down the oxidation process, which is enhanced in diabetic patients, and thereby treating the macrovascular complication of diabetes, would have been reasonably expected to be beneficial, absent evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
February 19, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

2/24/03